MillComp
File: m510ksum.doc
Date: May 4, 2001

DEC 0 4 2001

K011845

510(k) Summary

MillComp is a program that will write the tool path program to mill radiation therapy compensators on an end mill. Compensators are attenuators that are to be inserted into the x-ray beams for the purpose of modifying the field distribution over the area of the treatment beam. MillComp takes as input a compensator specification. The compensator specification will come from multiple sources, such as current therapy treatment planning systems, and is converted into a standard specification file format that MillComp can read. The conversion programs to read a compensator specification and write out the standard file format will be written on an as need basis according to the customer's needs. MillComp will read the specification file, generate the surface defined in the specification, and compute the tool paths necessary to cut the surface in solid lead, cerrobend, or other material, on a three axis end milling machine.

Document Approved by: Wendel Dean Renner
Title: President Date:

Wendel Dean Renner
May 30, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2001

Mr. Wendel Dean Renner
President
Math Resolutions, LLC
5975 Gales Lane
COLUMBIA MD 21045

Re: K011845
Trade/Device Name: Millcomp Version 1.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: September 18, 2001
Received: September 20, 2001

Dear Mr. Renner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MillComp
File: 4 May 2001
Date: minduse.doc

K011845

510(k) number:
Device name: MillComp
Indications for Use:

MillComp is used to manufacture compensators that are designed for radiation therapy treatment beams. MillComp may be used with any system that can design compensators such that the thickness over the area of the beam is specified at some known source to compensator distance in a plane perpendicular to the central axis. The thickness on an evenly spaced grid may be specified on divergent rays or on rays perpendicular to the plane of the compensator which is perpendicular to the central ray. If on divergent rays, the milled surface may be specified as towards the x-ray source or as towards the patient.

Document Approved by: Wendel Dean Renner
Title: President Date: May 30, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011845